

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE, INC., a Delaware corporation,)	
)	
)	
Plaintiff,)	C.A. No. 05-590 (GMS)
)	
v.)	
)	REDACTED PUBLIC VERSION
DEXCOM, INC., a Delaware corporation,)	
)	
Defendant.)	
)	

DECLARATION OF TIMOTHY GOODNOW

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ABBOTT DIABETES CARE, INC.,)
a Delaware corporation,)
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 Plaintiff,) C.A. No. 05-590 (GMS)
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DEXCOM, INC.,)
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 Defendant.)

DECLARATION OF TIMOTHY GOODNOW

1. My name is Timothy Goodnow, and I am over 18 years of age. If called upon, I could testify to the truth of the following facts based on my personal knowledge.

2. I am currently an employee of Abbott Diabetes Care, Inc., and my title is Divisional Vice President for Research and Development. My responsibilities include overseeing Abbott's development of new products and efforts to obtain FDA approval for such products. In performing these responsibilities, I analyze sales projections, study the impact new products may have on the market, analyze potentially competing products to determine the impact such products may have on the market for Abbott's products, prepare submissions to the FDA, and participate in written and oral communications with the FDA.

3. Over the course of my career, I have been involved in the development of at least 100 new products and dozens of applications for FDA approval. My involvement has included developing and gathering relevant information for submission to the FDA, designing and conducting clinical studies, drafting sections of PMA applications,

working closely with Abbott's regulatory affairs department, participating in FDA audits, communicating directly with the FDA, and participating in milestone meetings and hearings with the FDA such as 100-day meetings and panel hearings.

4. Abbott's FreeStyle Navigator™ Continuous Glucose Monitoring System (the "FreeStyle Navigator") represents Abbott's achievement over a number of technical barriers and will significantly change the way diabetics manage and deal with their disease.

5. Currently, the overwhelmingly most common method for patients to monitor glucose levels is by drawing blood several times per day by finger pricking. The finger prick method is a painful and inconvenient process that merely provides a snapshot of glucose levels at a particular point in time.

6. FreeStyle Navigator involves a three-part system that is designed to measure glucose levels as frequently as once per minute without the use of finger pricking. The first part of the system involves a sensor attached to a plastic sensor mount with adhesive to adhere to the skin (like a patch). The sensor is placed just under the skin by a disposable self-insertion device. The second part of the system involves a transmitter, designed to snap into the sensor mount on the skin's surface. The transmitter sends information wirelessly. The third part of the system involves a receiver that receives information wirelessly from the sensor/transmitter every minute. The receiver is designed to display glucose values, directional glucose trend arrows, and rate of change. The device also includes an alarm feature, which alerts the patient to possible dangerous trends, such as rapid blood glucose descents that may lead to hypoglycemia or ascents which may lead to hyperglycemia.

7. Abbott's work leading to the ultimate development of FreeStyle Navigator began over a decade ago in the early 1990's, beginning with work on sensor technology by Abbott's predecessor, Therasense. In total, Abbott has spent hundreds of millions of dollars inventing and developing the FreeStyle Navigator.

8. Abbott currently is seeking replacement approval from the FDA for FreeStyle Navigator, which means that patients who use Abbott's product will no longer need to prick their fingers several times per day to test their glucose levels. Occasional finger pricks will be required only for purposes of calibrating the device. Abbott expects FDA approval of Freestyle Navigator within the next ten months.

9. Abbott disclosed confidential information concerning its work developing FreeStyle Navigator to DexCom pursuant to a Confidential Disclosure Agreement during meetings in 2000 and 2001. This agreement does not permit DexCom to utilize Abbott's technology for commercial purposes. Moreover, the general fact that Abbott was working on multi-day glucose sensors was fairly well known as of 2000, and probably well before that as well.

10. DexCom's product, the STS™ Continuous Glucose Monitoring System, is nearly identical to FreeStyle Navigator, and would directly compete with FreeStyle Navigator.¹

11. Unlike Abbott's product, however, DexCom is seeking adjunct approval from the FDA for its product, meaning that it could be used only as a supplement to

¹ Another continuous glucose monitoring device, the Guardian RT™, has been launched by Medtronic in a limited geographic area in only five cities, and Abbott does not expect Medtronic to attempt significantly wider geographic market penetration. This device has a different configuration from Abbott's and DexCom's products; significantly, the sensor is attached to the monitor by a cord.

finger prick monitoring. Patients using DexCom's product will still need to rely on finger prick tests as the primary source of glucose monitoring. Obtaining adjunct approval from the FDA takes less time because the FDA conducts a less rigorous review of the product than it would if replacement approval were sought. For example, the FDA requires a panel review when a company seeks replacement approval; panel review is not mandatory when adjunct approval is sought. If, like DexCom, Abbott ever decided to seek lower level adjunct labeling, rather than replacement labeling, the FDA has indicated that FreeStyle Navigator could be approved rapidly, perhaps within months.

REDACTED

13. DexCom's attempt to launch a less accurate product as an adjunct to finger prick monitoring is of great concern to Abbott, because DexCom's launch could spoil the market for Abbott's more accurate product. If patients learn they cannot rely on continuous monitoring systems – because of inaccurate results and because patients will still be required to finger prick – patients will think that the method is inadequate, thereby tainting the technology as inferior. This is one of the reasons Abbott is not currently seeking adjunct labeling.

14. Abbott believes that DexCom's launch would have a negative impact on the market given its proposed adjunct labeling and inferior accuracy. Abbott may be required to spend millions of marketing dollars to educate the market, and these efforts might never be entirely successful.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct



Timothy Goodnow

CERTIFICATE OF SERVICE

I hereby certify that on March 22, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw
YOUNG CONAWAY STARGATT & TAYLOR LLP
1000 West Street, 17th Floor
P.O. Box 391
Wilmington, DE 19899-0391

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on March 22, 2006 upon the following individuals in the manner indicated:

BY HAND

John W. Shaw
YOUNG CONAWAY STARGATT & TAYLOR LLP
1000 West Street, 17th Floor
P.O. Box 391
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/s/ James W. Parrett, Jr.

James W. Parrett, Jr. (#4292)